NOV 22 2013

2. 510(k) Summary

Submitter: Redsense Medical AB
Gyllenhammars väg 26
302 92 HALMSTAD
SWEDEN

Contact Information: Mr.PatrikByhmer
Patrik.byhmer@redesensemedical.com

Submission Date: February 28, 2013

Device Name/trade name and Classification: Redsense alarm system, Class II, 21 CFR 876.5820 and product code ODX

Equivalent Device Identification:

Redsense Medical alarm unit K103242
Redsense Medical home use K092955

Device Description: Redsense Medical provides a system for monitoring the blood access during haemodialysis consisting of an alarm unit and a sensor connected to a specifically developed patch. The Redsense Patch uses integrated optic fibers to detect blood leakage from wounds. The optic fiber is connected to the sensor and alarm unit. If blood leakage occurs during haemodialysis, the patch surrounding the vein needle registers the event and changes a light signal to the alarm unit. This immediately activates a light and an alarm signal. Thus if a vein needle comes out of place extensive blood leakage is prevented.

Intended Use:
The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment. The device includes a blood sensor incorporated into a sensor patch. The sensor monitors potential blood leakage from the venous needle blood access via a light signal and will alarm if blood leakage is detected by the device's sensor.

Comparison Table

	Redsense alarm system	Redsense alarm unit	Redsense home use
Used	Home/self+ clinic	Clinic	Home/self
Usage time	NA (not battery operated)	8h	5h
510(k) number	New (k130554)	K103242	K092955
Intended use	The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment. The device includes a blood sensor incorporated into a sensor patch. The sensor monitors potential blood leakage from the venous needle blood access via a light signal and will alarm if blood leakage is detected by the device's sensor.	The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 8 hours in the clinical settings. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.	The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment up to 5 hours at home or in the clinical setting. The device includes a blood sensor incorporated into an adhesive dressing. The sensor monitors potential blood leakage from the needle puncture via an infrared light and will alarm if needle dislodgement or blood leakage is detected. All use must be administrated under physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.
Manufacturer	Redsense Medical	Redsense Medical	Redsense Medical
Audible Alarm	Complying with IEC 60 601-2-16 51,107;	Complying with IEC 60 601-2-16 51,107;	Complying with IEC 60 601-2-16 51,107;

	Requirements= 65dB(A) at 1 m Sound test report = 72 dB(A) at 1m	*Requirements= 65dB(A) at 1 m* Sound test report = 72 dB(A) at 1m	*Requirements= 65dB(A) at 1 m* Sound test report = 72 dB(A) at 1m
Operation power	Power supply	Internal rechargeable battery	Internal rechargeable battery
EMC requirements	Fulfills IEC 60601-1-2:2001 and IEC 61000-6-1 (for Medical devices + home use)	Fulfills IEC 60601-1-2:2001 and IEC 61000-6-1 (for Medical devices + home use)	Fulfills IEC 60601-1-2:2001 and IEC 61000-6-1 (for Medical devices + home use)
Type of Clinical trial obtained	No new clinical data. Same as K071013 used.	No new clinical data. Same as K071013 used.	No new clinical data. Same as K071013 used.
Electrical contact	Standard US electrical outlet (power supply)	Standard US electrical outlet (charger)	Standard US electrical outlet (charger)
Sensor used	New Redsense sensor	Redsense Sensor	Redsense Sensor

Discussion with respect to predicate devices

The Redsense alarm system is not battery operated, has two material changes (skin contact material), the sensor is slightly re-designed and can be used both at the clinic and at home. There is one predicate device k071013 manufactured by Redsense Medical as well not part of the table above but is also very similar in the technique and material. The predicate devices above rely on the clinical user evaluation data for the k071013 as well as some of the materials and so does the new device.

The new sensor operates on the same optical principle but is designed differently to be able to automate the production. This will reduce operator introduced risks as well as provide a better more stable production process. Instead of a bend of a thinner optical fiber we use a thicker which has been processed with a tip that will cause the same physical phenomena as with a bend of the fiber.

The redesign of the patch is that we use two materials that are flexible thus easier to place over a fistula that bulges. Also we use a larger absorbent patch so that the placement of the sensor becomes more forgiving.

All devices refer to the same clinical evidence presented in K071013. The changes we have made for the subject device are driven mainly by user feed-back. The clinical evaluations we have made is to confirm that the users can handle the device and understand it use. The ability to detect blood is validated in non-clinical test.

The major reason for change in the software is due to the change in power management. The predicate device was driven from a rechargeable battery. The subject device is **not** battery driven but instead supplied continuously from the power socket. For example the alarm algorithm for detecting blood is the same as is the failure handling in the software (i.e. low power, faulty signals etc).

Summary of Testing:

Verification testing has been performed to verify that the Redsense Alarm system device fulfills the Requirement Specifications. The electrical safety and EMC are fulfilled as well as the biocompatibility of the material and the performance.

Conclusion: Redsense Alarm system is similar in function and intended use to the Redsense Medical k071013, Redsense Alarm unit k103242 and home use device k092955. Verification and user evaluation show the Redsense systems to be safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Redsense Medical AB
Patrik Byhmer
CEO
Gyllenhammars väg 26
Halmstad 30292
Sweden

Re: K130554
Trade/Device Name: Redsense Alarm System
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: ODX
Dated: October 14, 2013
Received: October 17, 2013

Dear Patrik Byhmer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130554

Device Name
Redsense Alarm System

Indications for Use *(Describe)*
The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment. The device includes a blood sensor incorporated into a sensor patch. The sensor monitors potential blood leakage from the venous needle blood access via a light signal and will alarm if blood leakage is detected by the device's sensor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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